

**REMARKS/ARGUMENTS**

Claims 84-114 are pending in the above-referenced patent application; claims 84-90 are currently under examination, and claims 91-114 have been withdrawn from consideration as being directed to a non-elected invention pursuant to a Restriction Requirement.

Applicants acknowledge, with appreciation, the Examiner's indication that claim 90 is allowable, and that claims 85 and 86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In the Office Action, minor objections were made relating to the title of the invention and the abstract of the disclosure. In addition, claims 84 and 87-89 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. For the reasons set forth below, the objections to the specification and the rejection of the claims is overcome.

**Objections—Minor Informalities**

In the Office Action, the title of the invention and the Abstract of the Disclosure were objected to for minor informalities, *i.e.*, being too long in length. As set forth below, both the title of the invention and the Abstract of the Disclosure have been amended to address the informalities noted by the Examiner.

a. In the Office Action, the Examiner objected to the titles of the invention as being too long. In order to expedite prosecution, the title of the invention has been amended to make it more descriptive of the claimed invention and to shorten it in length. As amended, the title of the present invention is now "Fluorogenic Materials and Uses Thereof." In view of the amendment to the title, the Examiner's objection is overcome. Accordingly, Applicants urge the Examiner to withdraw this objection.

b. In the Office Action, the Examiner has objected to the Abstract of the Disclosure as being too long. In order to expedite prosecution, the Abstract of the Disclosure has

been amended so that it is descriptive of the disclosed invention, but that it meets the length limitation requested by the Examiner. As amended, the Abstract of the Disclosure recites:

"A method is presented for the preparation and use of fluorogenic peptide substrates that allows for the configuration of general substrate libraries to rapidly identify the primary and extended specificity of enzymes, such as proteases. The substrates contain a fluorogenic-leaving group, such as 7-amino-4-carbamoylmethyl-coumarin (ACC). Substrates incorporating the ACC leaving group show comparable kinetic profiles as those with the traditionally used 7-amino-4-methyl-coumarin (AMC) leaving group. The bifunctional nature of ACC allows for the efficient production of single substrates and substrate libraries using solid-phase synthesis techniques.

In view of the amendment to the Abstract of the Disclosure, the Examiner's objection is overcome. Accordingly, Applicants urge the Examiner to withdraw this objection.

**Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 84 and 87-89 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In support of this rejection, the Office Action, in essence, alleges: (1) "the generic statements R<sup>15</sup> is a member selected from the group consisting of -C(O)-AA and -C(O)-PP do not provide ample written description for the compounds since the claims do not describe a single structural feature" (*see*, page 7 of the Office Action); (2) "the specification does not clearly define or provide examples of what qualify as compounds of the claimed invention" (*see*, page 7 of the Office Action); and (3) "the specification does not describe any examples of -C(O)-AA and -C(O)-PP at R<sup>15</sup> (*see*, page 8 of the Office Action). Applicants respectfully disagree with the allegations put forth in the Office Action and, for the reasons set forth below, Applicants submit that claims 84 and 87-89 fully satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

As set forth in MPEP § 2163(II)(A)(3)(a)(ii), an adequate disclosure of a claimed genus depends on whether one of skill in the art would recognize that the Applicant was in possession of the necessary common features of the elements of the members of the genus. Possession can be shown by describing sufficient distinguishing characteristics (*see, e.g.,* MPEP

§ 2163(I), citing *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 48 USPQ2d 1641 (1998); *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); and *Amgen Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, USPQ2d 1016 (Fed. Cir. 1991)). A functional description of known compounds in the specification may be a sufficient description of the identifying characteristics of a claimed genus. See, MPEP § MPEP § 2163(II)(A)(3)(a)(ii), citing *In re Smythe* 480 F.2d 1376, 178 USPQ 279 (CCPA 1973). Moreover, as held in *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002), “[i]t is not correct . . . that all functional descriptions of genetic material fail to meet the written description requirement.” In *Enzo*, the Federal Circuit, referring to the USPTO Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112 ¶1, “Written Description” Requirement (66 Fed. Reg. 1099 (January 5, 2001)) held that the written description requirement is satisfied by a disclosure of relevant identifying characteristics, including functional characteristics coupled with a disclosed correlation between that function and a structure that is “sufficiently known or disclosed.” *Id.*

It is well-settled that the disclosure of a single species may support a genus. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323, 326-27 (CCPA 1981); *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979). The Federal Circuit recently affirmed the holding of *In re Smythe* that species representative of genus claims are descriptive of such claims.” *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1615 (Fed. Cir. 2002).

With respect to the first issue, Applicants respectfully submit that those of skill in the art would clearly understand that the phrase “R<sup>15</sup> is a member selected from the group consisting of -C(O)-AA and -C(O)-PP” is intended to mean that either (i) a single amino acid or (ii) a peptide sequence is covalently coupled, *i.e.*, attached, to the fluorogenic moiety set forth in claim 1. Those of skill in the art are familiar with the terms “amino acid” and “peptide sequence” and their art-recognized meanings. The specification and claims use these terms consistent with their art-recognized meanings. The term “amino acid” is self-explanatory. A single amino acid is coupled to the fluorogenic moiety. Equally self-explanatory is the term “peptide sequence.” With respect to the latter, however, the specification provides additional information regarding the meaning of this term and, importantly, provides a more detailed definition of this term. As pointed out in the Office Action, the specification further provides that in certain embodiments,

the peptide sequence has the formula:  $-C(O)-AA^1-AA^2-(AA^3)_{1-2}$ , wherein the variable set forth in this formula are defined in the specification. As such, the specification provides explicit information regarding the structure of the polypeptide sequence. Thus, as set forth in both the specification and claims (*see, e.g.*, claim 1), the common features of the presently claimed fluorogenic materials are (1) they comprise a fluorogenic material linked to a solid support, wherein the fluorogenic material has the structure set forth in, *e.g.*, claim 1; and (2) they comprise either a single amino acid or a peptide sequence that is covalently coupled, *i.e.*, attached, to the R<sup>2</sup> position of the fluorogenic moiety set forth in, *e.g.*, claim 1. The description of these common features in both the specification and claims provides more than adequate written description for the claimed invention. Clearly, based on the description of these common features, one of skill in the art would clearly understand what is intended by the claimed invention.

With respect to the second and third issues, Applicants respectfully submit that the specification does provide examples of the presently claimed fluorogenic materials and details methods for preparing such fluorogenic materials. For instance, Example 1 sets forth an illustrative synthetic route for the preparation of an exemplary ACC-resin. In addition, Example 2 provides an illustrative synthesis of a solid support and the functionalization of the solid support with a single amino acid residue. As set forth in Example 2, the Fmoc-ACC resin was functionalized with 20 different single amino acids. Similarly, Example 3 sets forth the synthesis and screening of libraries of the presently claimed fluorogenic materials, wherein various polypeptide sequences (polypeptide sequences comprising AA<sup>1</sup>, AA<sup>2</sup>, AA<sup>3</sup> and AA<sup>4</sup>) were coupled to the fluorogenic moiety, and the libraries were screened for enzymatic activity. Example 4 also sets forth the synthesis and screening of libraries of the presently claimed fluorogenic materials, wherein various polypeptide sequences were coupled to the fluorogenic moiety, and the libraries screened for enzymatic activity. Examples 5 and 9 set forth the synthesis of single peptide substrates and the screening of these substrates for kinetic properties. Example 8 provides an example of positional scanning of synthetic combinatorial libraries, wherein various polypeptide sequences were coupled to the fluorogenic moiety and screened for activity. Other examples detailing the preparation and screening of libraries of the presently

claimed fluorogenic materials, wherein either an amino acid or a polypeptide sequence are coupled to the fluorogenic moiety, are provided. Based on the teachings of the specification, together with the numerous working examples provided, Applicants respectfully submit that the specification provides more than adequate written support for the subject matter presently claimed. Clearly, one of skill in the art would recognize that the Applicants were in *clear* "possession of the necessary common features of the elements of the members of the genus," and, thus, that the claims satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

In view of the foregoing, Applicants respectfully submit that the Examiner's concerns have been overcome. Accordingly, Applicants urge the Examiner to withdraw this rejection.

#### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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